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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CLASSIFICATION NO.
09/903,770	07/13/2001	Bettina Moeckel	203979US0X	1467

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

BEST AVAILABLE COPY

Office Action Summary

Application No.
09/903,770

Applicant(s)
Moeckel et al.

Examiner
Christian L. Fronda

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 9, 11-13, 22, and 40-52 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 11-13, 22, and 40-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jul 13, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10, 14 6) ☐ Other:

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DETAILED ACTION

1. Claims 1-4, 8, 9, 11-13, 22, and 40-52 are under consideration in this Office Action.

Information Disclosure Statement

2. The information disclosure statement filed 11/06/2001(Paper No. 5) fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.
3. The information disclosure statement filed 01/30/2001 (Paper No. 10) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-4, 8, 9, 11-13, and 40-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
The claims encompass all polynucleotides which encode any protein comprising the amino acid sequence of SEQ ID NO: 3, all polynucleotides comprising nucleotides 201-1109 of SEQ ID NO: 1, all polynucleotides which hybridize to nucleotides 201-1109 of SEQ ID NO: 1, all polynucleotides comprising 15 to 383 consecutive nucleotides of SEQ ID NO: 1, all polynucleotides consisting essentially of any polynucleotide that encodes a protein of SEQ ID

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NO: 2, and any polynucleotide comprising SEQ ID NO: 3. The specification only discloses SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 3 as representative species of the claimed invention. However, the specification does not provide a written description of any structure to function or activity relationship or the nucleotide sequence that is 5' and 3' of the claimed polynucleotides. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

6. Claims 22, 43, and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention of claims 22, 43, and 44 appear to employ a novel gene, vector, and host cell. Since they are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmid's sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be biblically known and freely available. The requirements of 35 U.S.C. 112, 1st paragraph may be satisfied by deposit of the plasmid and host cell. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the plasmid and host cell should have been made in accordance with 37 C.F.R. 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

- (1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

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- (3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (4) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, 3, 8, 9, 12, 40, 47, 49, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that SEQ ID NO: 3 is an amino acid sequence. However, the "Sequence Listing" states that SEQ ID NO: 3 is a nucleotide sequence and SEQ ID NO: 2 is an amino acid. Claim 1 indefinite because the specific amino acid sequence and nucleotide sequence claimed is not known. Claims 2, 12, and 47 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

In claim 3, the phrase "degenerates thereof" renders the claim vague and indefinite because the meaning of the phrase is not known and not defined in the specification. Claims 8 and 9 which depend from claim 3 are also rejected because they do not correct the defect of claim 3.

Claim 8 is vague and indefinite because the specific reference sequence to which the claimed polynucleotide will hybridize to under the recited conditions are not known and not defined and the specific temperature for the hybridization is not known.

In claims 2 and 9, the phrase "LysR1 transcriptional regulatory activity" renders the claim indefinite and ambiguous because the specific activity which is regulated by the claimed polypeptide is not known and not defined in the specification. Claims 47 and 51 which depend from claims 2 or 9 are also rejected because they do not correct the defect of claims 2 or 9.

In claim 40, the phrase "consisting essentially of" renders the claim vague and indefinite because it is not known if the claimed polynucleotide consists or comprises a part or the entire nucleotide sequence encoding SEQ ID NO:2. The metes and bounds of the claimed invention cannot be determined.

In claim 49, the phrase "polynucleotide of claim 7" renders the claim vague and indefinite because it depends from a canceled claim.

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Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Ventura et al. Ventura et al. (GenBank Accession AF098867) teach a polynucleotide that has 20 contiguous nucleotides that are identical to the nucleotide sequence of SEQ ID NO: 1 (see Alignment No. 1). Thus, the reference teachings anticipate the claimed invention.

Conclusion

11. No claim is allowed.


12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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